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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/506,081	02/16/2000	Jessica Chiu	003764.P025	5716

7590

02/14/2006

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EXAMINER

LACYK, JOHN P

ART UNIT

PAPER NUMBER

3735

DATE MAILED: 02/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

28

Office Action Summary

Application No.

09/506,081

Applicant(s)

CHIU ET AL.

Examiner

John P. Lacyk

Art Unit

3735

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-142 is/are pending in the application.
- 4a) Of the above claim(s) 54-79 and 106-142 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-53 and 80-105 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>6/26/00; 5/22/00</u> . | 6) <input type="checkbox"/> Other: _____ |

1. Applicant's election of Species 2, Figure 6, claims 1-53, 80-105 in the reply filed on 08/29/05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 54-79 and 106-142 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 08/29/05.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 1-12, 15-21, 27-38, 41-47, 53 and 80-87, 90-100 are rejected under 35 U.S.C. 102(e) as being anticipated by Loffler et al.

Art Unit: 3735

Loffler et al discloses a multi-lumen balloon catheter assembly for centering a radiation source. The Loffler et al device has a plurality of inflatable outer lumens or balloons (6-11) that can be connected to a central lumen (2), the balloons can be inflated by one or more channels arranged in the tube. The device has a catheter shaft has a central channel (3) that is adapted to receive a radiation source and another channel (4) or lumen for receiving a guidewire. The balloons are inflated to center the radiation source with respect to the wall of the blood vessel (column 3, lines 49-56). With the balloons using separate channels to inflate plurality of balloons, each of the balloons is capable of being inflated to whatever pressure is desired, which would inherently move the central channel to center it however is desired. The plurality of balloons (Figure 2) form straight longitudinal paths (18) that allow for the perfusion of blood to pass when the device is in use and are considered to form a "fluted" shape.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 22-25, 48-51, 101-104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loffler et al.

Although Loffler et al does not recite the specific size of the treatment area (i.e. the longitudinal length and the combined diameter) this is considered to be directed to a matter of routine engineering design choice base upon the size of the area that is to be

Art Unit: 3735

treated and the size of the specific persons blood vessels, further since the balloons are inflatable the diameter would change depending on how much the balloons are inflated.

7. Claims 13-14, 39-40 and 88-89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loffler et al in view of Klein (5,863,284).

Loffler et al discloses the claimed device except for the use of markers to mark the treatment area. Klein teaches that it is well known in the radioactive therapy art to provide markers on the treatment device to mark the location of the device in the body to ensure proper placement of the device in the treatment area. Therefore a modification of Loffler et al to include such markers would have been obvious since this would allow the user to ensure proper placement of the device in the treatment area.

8. Claims 26, 52, 105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loffler et al in view of Voyles et al (6,540,721).

Loffler et al discloses the claimed device except for device being made from nylon, or pebax. Voyles et al teaches (column 4, lines 49-52) that it is well known to manufacture such device using nylon or pebax. Therefore a modification of Loffler et al such that the device is made from nylon or pebax would have been obvious in view of the teachings of Voyles et al.

9. The information disclosure statement filed 05/22/00 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each

non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. The US references have been considered, however there appears to be no copies of the foreign patent documents of the non-patent literature publications and therefore these have not been considered at this time.

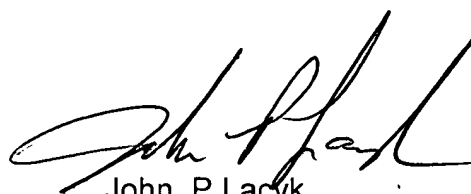
10. The information disclosure statement filed 07/16/02 fails to comply with 37 CFR 1.98(a)(1), which requires the following: (1) a list of all patents, publications, applications, or other information submitted for consideration by the Office; (2) U.S. patents and U.S. patent application publications listed in a section separately from citations of other documents; (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement. The information disclosure statement has been placed in the application file, but the information referred to therein has not been considered. There appears to be no PTOL-1449 listing the references to be considered and/or no copies as stated above.

Art Unit: 3735

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P. Lacyk whose telephone number is 571-272-4728. The examiner can normally be reached on Mon-Fri, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ali Imam can be reached on 571-272-4737. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'John P. Lacyk', is positioned above the printed name and title.

John P Lacyk
Primary Examiner
Art Unit 3735

J.P. Lacyk